BRONTUSS SF-NR- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid
Portal Pharmaceutical

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Brontuss SF-NR

Drug Facts
Active ingredients
(in each 5 mL teaspoonful)
Dextromethorphan Hydrobromide 15 mg
Guaifenesin 300 mg
Phenylephrine Hydrochloride 10 mg

Purpose
Antitussive
Expectorant
Nasal Decongestant

Uses
Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- helps phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passages

Warnings
Do not exceed recommended dosage.

Do not use this product

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema
- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
Do not exceed recommended dosage.

Adults and Children 12 years of age and over:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 doses in 24 hours.
Children 6 to under 12 years of age:	1/2 teaspoonful (2.5 mL) every 4 hours, not to exceed 6 doses in 24 hours.
Children under 6 years of age:	Consult a doctor.

Other information
- Each 5 mL teaspoonful contains 5 mg sodium.
- Store at 59°-86° F (15°-30° C)

Inactive ingredients
citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions? Comments?
Call your doctor for medical advice about side effects. Serious side effects associated with this product may be reported to this number.
Call (787) 832-6645. Operation Hours: Monday - Friday, 8 A.M. to 4 P.M. Atlantic Standard Time (AST)
portalpharmaceutical@gmail.com

Manufactured for:
Portal Pharmaceutical
Mayaguez, PR 00681

Rev. 11/11

Product Packaging
The packaging below represents the labeling currently used.

Principal display panel and side panel for 30 mL label:

NDC 49963-381-01

Brontuss
SF-NR
Liquid

· Antitussive · Expectorant
· Nasal Decongestant

Each teaspoonful (5 mL) for oral administration contains:
Dextromethorphan HBr.....15 mg
Guaifenesin.....300 mg
Phenylephrine HCl.....10 mg

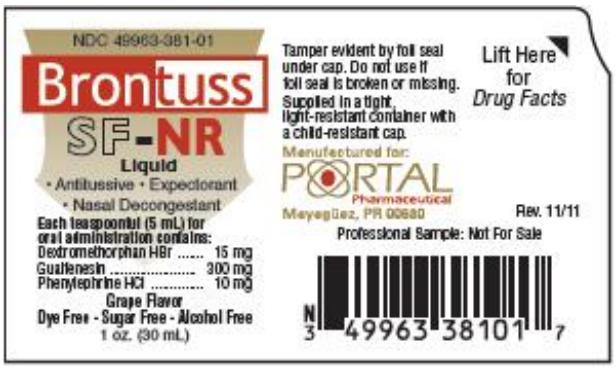
Grape Flavor
Dye Free · Sugar Free · Alcohol Free

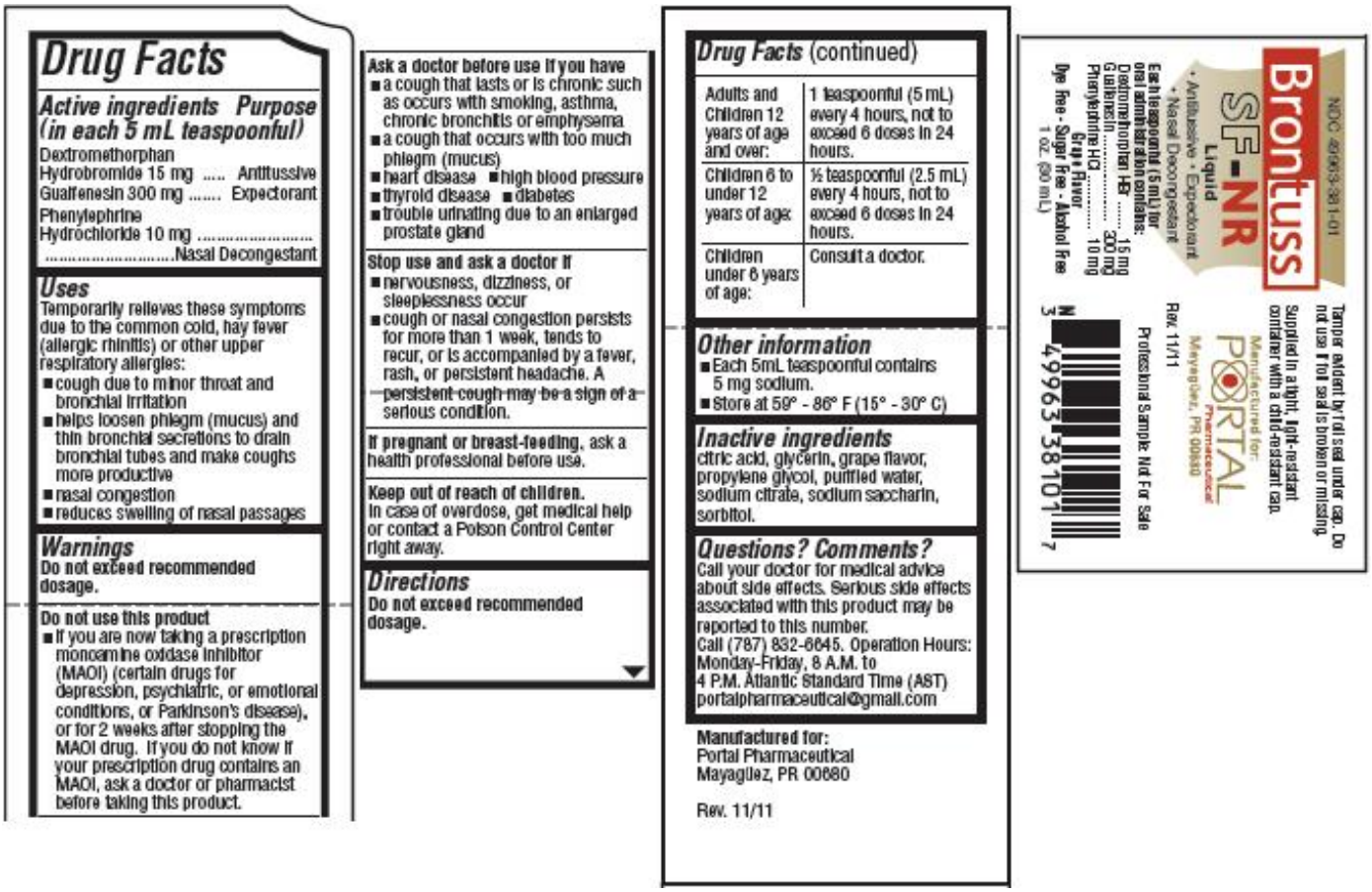
1 oz. (30 mL)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
Supplied in a tight, light-resistant container with a child-resistant cap.

Manufactured for:
PORTAL
Pharmaceutical
Mayaguez, PR 00680 Rev. 11/11

Professional Sample: Not For Sale





Drug Facts

Active ingredients Purpose (in each 5 mL teaspoonful)

Dextromethorphan Hydrobromide 15 mg ..... Antitussive
Guaifenesin 300 mg ..... Expectorant
Phenylephrine Hydrochloride 10 mg ..... Nasal Decongestant

Uses

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have
- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema
- a cough that occurs with too much phlegm (mucus)
- heart disease - high blood pressure
- thyroid disease - diabetes
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not exceed recommended dosage.

Drug Facts (continued)

Adults and Children 12 years of age and over:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 doses in 24 hours.
Children 6 to under 12 years of age:	½ teaspoonful (2.5 mL) every 4 hours, not to exceed 6 doses in 24 hours.
Children under 6 years of age:	Consult a doctor.

Other information
- Each 5mL teaspoonful contains 5 mg sodium.
- Store at 59° - 86° F (15° - 30° C)

Inactive ingredients

citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions? Comments?

Call your doctor for medical advice about side effects. Serious side effects associated with this product may be reported to this number.
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portalpharmaceutical@gmail.com

Manufactured for:
Portal Pharmaceutical
Mayaguez, PR 00680

Rev. 11/11

NDC 49963-381-01

Brontuss SF-NR Liquid
- Antitussive - Expectorant
- Nasal Decongestant

Each teaspoonful (5 mL) for oral administration contains:
Dextromethorphan HBr ..... 15 mg
Guaifenesin ..... 300 mg
Phenylephrine HCl ..... 10 mg
Grape Flavor
Dye free - Sugar free - Alcohol free
1 oz. (30 mL)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
Supplied in a tight, light-resistant container with a child-resistant cap.

Rev. 11/11

Manufactured for:
PORTAL Pharmaceutical
Mayaguez, PR 00680

Professional Sample Not For Sale

N 3 49963 38101 7

BRONTUSS SF-NR

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49963-381
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	15 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	300 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49963-381-01	30 mL in 1 BOTTLE		
2	NDC:49963-381-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/22/2011	

Labeler - Portal Pharmaceutical (831005199)

Registrant - Great Southern Laboratories (056139553)

Establishment

Name	Address	ID/FEI	Business Operations
Great Southern Laboratories		056139553	manufacture

Revised: 12/2011 Portal Pharmaceutical